Reviewer’s report

Title: Consent and community engagement for school-based health research in Africa: experiences from a cluster randomised impact evaluation on the Kenyan south coast

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Reviewer: sarah edwards

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The research topic is new but it wasn’t clear exactly what the study was intending to show. The main claim of the paper seemed to be that community engagement strengthens informed consent.

The methods used seemed to fluctuate between anecdotal observations of authors themselves to list their challenges associated with recruiting to the trial, or more analysis of qualitative interviews previously conducted and published to fit the stated topic of the paper. The qualitative interviews, however, did not seem to have included any parents or children for their views on either the value of community engagement or the success of the consent process.

There was insufficient reporting of the qualitative data to substantiate many of the authors’ claims. In fact, community engagement involved ‘constant communication’ which could have applied pressure to threaten consent which the authors did not recognise and discuss. For example, those not consenting at a public meeting were subsequently traced and approached at home under ‘follow-up visits’. In defence of this approach, the authors claim that a one-to-one interview at home enabled the researcher to better communicate with the potential recruit than in a public meeting, which makes one wonder why consent from others at the public forum was accepted at all. Furthermore, they report that in rare cases mothers consented at public meetings but their situation and the possible need for the fathers consent was not fully discussed. In what sense was consent improved by community engagement and from whose point of view? Consent rates for scientific benefit and/or morally enhanced consent? As the parents voices are not reported it is hard to know.

The authors assert that as randomisation was done in public, transparency and trust were promoted. Again, this claim to have enhanced community trust is not substantiated with data.

Perhaps, the authors claim that consent is strengthened by improving the parents’ understanding of the trial. However, any assessment of understanding was not reported and, where results are reported, the authors quote contrary data from field workers or teachers. For example, some parents had apparently complained that the study was unable to fulfil their expectations. This was attributed by the authors either to a lack of understanding or the fieldworkers’ unduly raising their expectations. What didn’t seem to have been explained to anyone was the rationale for an effectiveness cluster trial of a treatment already
licensed and recommended for use in Kenya. Denying control clusters would then need to be justified. Without understanding that, randomisation makes little sense even if people are told that their cluster has been randomised. Understanding that the trial was a cluster trial was not mentioned.

In addition, inviting people merely to witness procedures in public to increase familiarity does not imply greater understanding and could rather reflect a cognitive bias. The data do not inform this question either way.

There is a quotation from a teacher given suggesting that the younger children were scared of the pin prick associated with the malaria treatment. The authors also comment that some teachers applied pressure to them (even threats) but the liaison team discouraged this. There is no way for us to gauge the extent of this problem. Furthermore, the authors do not say whether their intervention was successful in reducing coercion of the children. Some teachers, it is reported, pricked themselves to show it was ok. The authors assert from these data that over time, the children gained confidence and dissent became less of a problem.

There was not even a report of consent and participation rates let alone with and without the ‘benefits’ of community engagement. Neither were there qualitative data to suggest the community liaison group had any influence over consent rates or the moral quality of consent other than to identify issues.

There were some data which seemed irrelevant to the research question. The data on parents who did not see consent as necessary do not support the thesis. The discussion of fitting the literacy intervention in with the school syllabus and educational programme does not tie in with consent at all, as those assigned the literacy intervention were not given to option to refuse or dissent.

The Discussion does not analyse the ethics of cluster trials and the role of consent or assent in such research.

In sum, there was too much logistic detail about meetings to set up the trial and not enough on establishing the main claims concerning community engagement and the quality of consent and assent. While the writing is acceptable, I would recommend major revisions before this study is considered for publication.